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FEDERAL EXPRESS

October 20, 2004

Shellee Anderson
Team Leader
Nutrition Policy and Labeling Staff
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety
Department of Health and Human Services
Public Health Service
Food and Drug Administration
College Park, MD 20740

RE: 2004O-0151: Qualified Health Claim Petition: Soy Protein and Cancer

Dear Ms. Anderson:

This letter is to request to modify the above-referenced petition submitted by Solae, LLC (hereafter Solae). In particular, we propose to modify the health claim language based on (a) the language contained in qualified health claims approved by the FDA, and (b) consumer research conducted by Solae. We also request a meeting with your group to discuss the modified claim language, as well as the overall status of our petition.

As Qualified Health Claims have been authorized by FDA, it has become apparent that claim language other than that suggested in the *Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements* could be employed. Therefore we are requesting a change in claim language wording from our original petition. We are basing this change on research we conducted, which indicated an alternate form of the claim language enabled the consumer to more readily understand the relationship between soy protein consumption and the prevention of certain cancers, given the qualified statement regarding the science.





Solae developed several different forms of potential claim language and conducted consumer research. Results from this study indicated that the following statement was easiest to understand:

New scientific research suggests, but does not prove, that soy protein may reduce the risk of certain cancers.

Results also indicated that the following was easy to understand by consumers in the survey:

Soy protein may reduce the risk of certain cancers. The scientific evidence is promising but not conclusive.

The following statement scored very poorly in our preliminary testing and was not included in the final research:

Soy protein may produce anticarcinogenic effect in the body. Scientific evidence suggests that consumption of soy protein may produce anticarcinogenic effects in the body. However, this evidence is not conclusive.

Based upon the above mentioned research, we request that the health claim language for the Qualified Health Claim: Soy Protein and Cancer be modified as follows:

New scientific research suggests, but doe's not prove, that soy protein may reduce the risk of certain cancers.

and

Soy protein may reduce the risk of certain cancers. The scientific evidence is promising but not conclusive.

If FDA has concerns over the use and implications of the word "new" in the first statement, we recommend dropping this word (e.g. "Scientific research suggests, but does not prove, that soy protein may reduce the risk of certain cancers."). We would like to propose two options for claim language such that food manufacturers will have flexibility with regard to their specific market. A summary of the research is enclosed.

In addition Solae requests a meeting with FDA to discuss several key issues. First, we would like to address any questions or concerns regarding changing the claim language. Secondly, we would like to discuss any issues raised in response to our reply to the Weston Price Foundation Comment. Thirdly, we would like to discuss the timing and parameters of any announcement of the approval of a qualified health claim.

Thank you for your time and consideration.

Sincerely,

Susan M. Potter, Ph.D.

Global Director

Health and Nutrition

Solae, LLC

cc: Jean Heggie

Geri Berdak

Cary A. Levitt, Esq.

Gregory L. Paul, Ph.D.

Encl.



Topline Report

FDA Claim Sort II

Topline Report
October 2004
DUPO0020041



Introduction and Findings

Background & Objectives

Background

- The Solae Company has petitioned the FDA for a soy protein and cancer risk reduction qualified health claim. The FDA is currently evaluating the petition and will issue a final ruling on it by the end of the year.
- In its petition to the FDA, The Solae Company had included suggested on-pack claim language. Through consumer research, the Company wanted to determine whether the suggested language in its original petition was preferred and understood by consumers versus several other alternative claim statements. All statements tested in this study had a "qualifier" included in the statement, consistent with the Company's petition to the FDA for a soy protein and cancer risk reduction qualified health claim. This study looked at 6 (six) health claim statements, including one claim from the original petition. (The second claim from the original petition was not fielded in this study, as it was fielded in a similar consumer research project in July 2004 and determined to score low on all key dimensions with consumers.)

Objectives

- Determine which health claim (one from the original petition and 5 alternatives) is easiest for consumers to understand
- Look at other key measures evaluating the various health claims, to aid in this analysis, such
 as: motivation to buy, believability, uniqueness and determining if anything is confusing or
 difficult to understand

Summary of Method

Methodology:

Design/Method: Sort

Project: FDA Claim Sort II

Sample:

Test sample size: 310

Test sample source and type: Zoom Panel, Nationally Representative (balanced

on age, gender and income)

Test respondent qualifications:

Ages 18+

Field dates: 9/29/04 - 9/30/04

Analysis:

 Criteria for Recommendation: The health claim which has the highest percentage of "Easiest to Understand" score will be recommended

Recommendations

Recommendations

"New Research' is the winning health claim - based on the being 'Easiest to Understand' criterion

- "New scientific research suggests, but does not prove, that soy protein may reduce the risk of certain cancers."
- The words "New scientific research" seem to drive the appeal for this claim
- Beats other 5 claims evaluated on both 1st and 1st/2nd easiest to understand measures
- Particularly strong among those under age 55

As an alternative, "Claim/Promising" also tested well with consumers on the dimension "easy to understand"

- Some consumers seem to prefer to have the benefit statement first, with the qualified statement secondary.
- Versus "Claim/Original", written in a similar manner, "Claim/Promising" is perceived as being simpler and more to-the-point, less redundant and wordy.
- "Claim/Promising" was chosen as the 1st or 2nd easiest to understand by 38% of the respondents, compared to 46% for "New Research"

Claims Tested with Consumers -- September 2004

The following two pages include the claim language options tested in this study. Each is provided a heading or title which is how they are identified in the data tables that follow.

"Claim/Original" is one of the original claim language statements included in The Solae Company's original petition to the FDA. The other statement suggested in the original petition follows on page 9. This statement was tested in a similar study by The Solae Company in July 2004 but was not re-tested in this survey, as in the July 2004 it was determined to be "easiest to understand" by only 3% of respondents.

"New Research"

New scientific research suggests, but does not prove, that soy protein may reduce the risk of certain cancers.

"Claim/Original"

Soy protein may reduce the risk of certain cancers. Scientific evidence suggests that consumption of soy protein may reduce the risk of certain cancer. However, this evidence is not conclusive.

"Supportive"

Supportive, but not conclusive, research shows that consumption of soy protein may reduce the risk of certain cancers.

"Claim/Promising"

Soy protein may reduce the risk of certain cancers. The scientific evidence is promising but not conclusive.

"Promising"

Promising, but not conclusive, research suggests that soy protein may reduce the risk of certain cancers.

"Claim/Growing"

Soy protein may reduce the risk of certain cancers. A growing body of research suggests, but does not prove, that soy protein may reduce the risk of certain forms of cancer.

July 2004

Soy protein may produce anti-carcinogenic effects in the body.

Scientific evidence suggests that consumption of soy protein may produce anti-carcinogenic effects in the body. However, this evidence is not conclusive.

This claim language was included in the original petition by The Solae Company to FDA and was tested with consumers in a similar study design in July 2004. In that study, this language was chosen as "easiest to understand" by only 3% of the respondent base, so it was not retested in this study.

'New Research' Claim is Winner Based on Ease of Understanding

 'New Research' stands alone among these 6 health claims tested as being the one easiest to understand

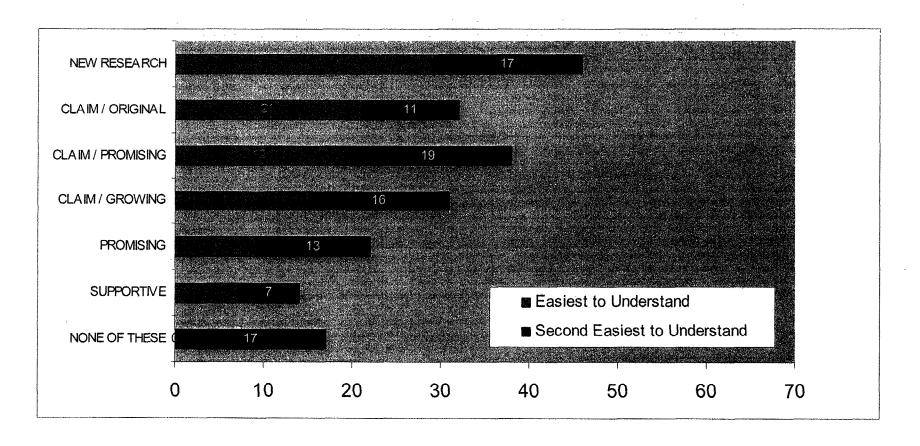
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SUMMARY TABLE - KEY MEASURES - S	UMMARY					
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3	NEW RESEARCH	CLAIM/ORIGINAL	CLAIM/PROMISING	CLAIM/GROWING	PROMISING	SUPPORTIVE
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Base: Total Respondents	310	310	310	310	310	310
	%	%	%	%	%	%
Conjunctive 1	22%	22%	21%	21%	15%	15%
	ef	ef	ef	f		
Conjunctive 2	16%	18%	16%	15%	12%	11%
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Easiest to Understand	29%	22%	19%	15%	9%	7%
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1st/2nd Easiest to Understand	\ 46% /	33%	38%	31%	22%	14%
	bcdef	ef	ef	ef	f	
Top 2 Box Understandable	72%	66%	71%	66%	60%	58%
	ef		ef			
Top 2 Box MTB	24%	25%	22%	24%	17%	17%
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Top 2 Box Believability	37%	37%	36%	32%	28%	31%
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Top 2 Box Uniqueness	18%	21%	18%	20%	16%	17%
Not Confusing/ Hard to Understand	95%	90%	94%	91%	92%	86%
	bdf		f	f	52.76 f	00 /0

Conjunctive 1 = Top 2 Box Understandable + Top 2 Box MTB

Conjunctive 2 = Top 2 Box Understandable + Top 2 Box MTB + Top 2 Box Believability + 'No' for Anything Confusing/Hard to Understand Note: Letters in the charts indicate statistically significant differences across columns at a 95% confidence level or greater.

'New Research' Health Claim Easiest to Understand

- 'New Research' is clearly the health claim which is easiest to understand
- This claim resonates particularly well among those under age 55



% Selecting as 1st or 2nd Easiest to Understand

Base: All respondents who viewed each option (n=310)



Conclusions/Recommendations

To ensure consumer understandability of claim language related to the soy
protein and cancer risk reduction qualified health claim, we recommend that
FDA consider the following statement as approved on-pack language for the soy
protein and cancer risk reduction qualified health claim:

New scientific research suggests, but does not prove, that soy protein may reduce the risk of certain cancers.

 If FDA has concerns over the use and implications of the word "new" in this statement, we recommend that they consider the following alternative, dropping the word "new":

Scientific research suggests, but does not prove, that soy protein may reduce the risk of certain cancers.

 As an alternative, we suggest that FDA consider approval of the following language related to the soy protein and cancer risk reduction qualified health claim, which also scored well with consumers on "understandability":

Soy protein may reduce the risk of certain cancers. The scientific evidence is promising but not conclusive.

October 22, 2004

Ms. Jennie C. Butler
Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

1102 °04 125 P2:07

RE: Qualified health claim petition: Soy Protein and Cancer (Docket No. 2004O-0151)

Dear Ms. Butler:

Please file the enclosed documents submitted by the Solae Company in Docket Number 2004Q-0151.

Thank you.

Sincerely,

Tomoko Shimakawa, Sc.D.

Tolio Shuchan

Division of Nutrition Programs and Labeling

Office of Nutritional Products, Labeling and Dietary Supplements

Center for Food Safety and Applied Nutrition

Food and Drug Administration

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Enclosure:

(1) Documents (received on October 22, 2004) submitted by the Solae Company.